



USDA Foreign Agricultural Service

# GAIN Report

Global Agriculture Information Network

Template Version 2.09

Voluntary Report - public distribution

**Date:** 10/23/2003

**GAIN Report Number:** SR3012

## Serbia and Montenegro

### Biotechnology

### Biotechnology Regulations

### 2003

**Approved by:**

Holly Higgins  
U.S. Embassy

**Prepared by:**

Tatjana Buric

---

**Report Highlights:**

Serbia and Montenegro apply relevant Yugoslav or federal laws governing biotechnology. Current law allows for testing and commercial release, but only two research approvals have been granted. Biotech crop/food oversight and enforcement remains unclear in practice. Imports of biotech soybeans and corn are prohibited. Soy and corn by-products are tested for biotech content and allowed entry on an ad hoc basis. Labeling is required but not enforced.

---

Includes PSD Changes: No  
Includes Trade Matrix: No  
Unscheduled Report  
Sofia [BU1]  
[SR]

---

## 2001 Federal Law

The Federal Yugoslav Parliament approved a law governing genetically modified organisms (GMOs) on May 8, 2001. Currently, Serbia and Montenegro apply the same Federal law at the level of each Republic. The laws --and rulebooks implementing the law-- have been designed to follow regulations of the European Union. Thus, technically the Yugoslav law and regulations (or rulebooks) are in complete accordance with EU directives 90/220 and 90/219.

## Major Regulations

Four regulations (Rulebooks) were issued during 2002.

- Commercial release of 'GMOs' or products derived from it - No.1245/1 issued 13 Nov 2002.
- Contained use of genetically modified organisms - No.1244/1 issued 13 Nov 2002.
- Deliberate release of biotech products into the environment - No.1246/1 issued 13 Nov 2002.
- Regulation on the content and data of products derived from GMOs - No. 1669/1 issued 15 Dec 2002.

## Research Rules

The 2001 Federal law allows research or use of biotech products, but put them under strict supervision of the state. Permits for work, research, contained use and marketing can be obtained by meeting the regulated requirements. The law regulates three fields: work under contained use (experimental use); deliberate use of GMO (production of GMO seeds which are prohibited for sales in country); and marketing of biotech events (allowed for sale locally).

## Application Process

Regulations (rulebooks) set forth the detailed application process for obtaining a permit. The application must provide all the necessary data on the particular biotech event or GMO; parameters for estimating safety; and safety measures. All applications are to be submitted to the Serbian or Montenegrin Ministry of Agriculture. Risk assessments are conducted by the National Council for Biological Safety, which is composed of representatives of scientific-research institutions in the fields of agricultural, ecological and biological sciences. Following the risk assessment and the scientific recommendation of the National Council, the Ministry of Agriculture, as the administrative authority in charge, must issue decrees on the specific biotech event. Every application is evaluated on a case-by-case basis. As of October 2003, the only applications approved are:

- Commercial import or trade of soybean meal obtained from Roundup Ready (RR) soybeans. RR soybeans for crushing or RR corn for commercial use are not allowed for import.
- Research (not to be released or marketed in country) conducted by two local institutes for Roundup Ready (RR) corn and introduction of Liberty Link into domestic corn varieties.

## Monitoring and Enforcement Authorities

The Serbian Ministry of Agriculture, Department for Genetic Resources is the main administrative authority in charge of monitoring biotechnology. Contact information: Serbian Ministry of Agriculture, Head of Department for Genetic Resources and GMO, tel: ++ 381 11 311 7588. The Montenegrin Ministry of Agriculture has no resources for agriculture biotechnology and generally follows decisions made by the National Biosafety Council and the Serbian Ministry of Agriculture.

The Ministry of Agriculture is authorized to supervise the application of the law and its subsequent regulations through a system of Republic inspectors. These field inspectors control and sample at the border and inland. A company or individual can be fined from 150,000 to 450,000 dinars (USD 2500 to 8000) if they are found to have allowed the release, production or trade of GMOs and products derived from GMOs for which no approval was issued by the legal authority.

## Import Shipments Tested

Imports of soybeans, soy meal and corn (and byproducts) are tested for biotech content at the border. Republic border inspectors sample every shipment and these samples are sent to one of three authorized laboratories for testing: Institute for Molecular Biology and Genetic Engineering (Belgrade), Corn Research Institute in Zemun Polje (Belgrade) and the Institute for Field and Vegetable Crops (Novi Sad). Detection of genetic modifications is PCR based.

## Traceability

Serbia and Montenegro have not implemented a traceability system for products from agriculture biotechnology. They lack the resources to fully implement this kind of system. There are no regulations with this requirement at present.

## Documentation

Documentation required for import of agricultural products which may contain the products of agriculture biotechnology must include an original certificate attached to the imported product, as issued by a certified control body from the country of origin, stating the specific biotech event and percent content.

Depending of the intended use, documents required for the application for approval of field testing; limited production or commercial trade with new biotech events are: 1) data necessary for risk assessment for commercial release; 2) brief content of the application or intended use; 3) risk assessment with all bibliographical data (references) and indications of the methods used in risk assessment (direct effects, indirect effects, immediate effects, delayed effects, cumulative long-term effects on humans and environment); 4) monitoring plan with the objective to confirm or deny any assumptions regarding the occurrence and impact of potential adverse effects of the products on human health and the environment.

## Field Testing

In-country field test are mandatory prior to regulatory approval of a new commercial, biotech crop. There are currently two approved field test programs. The first is Monsanto's joint research project on Roundup Ready corn with two Serbian institutes: Institute for Corn Research and Institute for Field and Vegetable Crops. In 2001, Monsanto was granted a four-year approval for this research. The second is Aventis' project with the same Serbian

institutes for introduction of Liberty Link events into domestic corn varieties. This project started in 1997 and is still active on 0.2 hectares. Neither project allows commercial release.

### Food Labeling

Labeling of foods is under the responsibility of the Republic Ministry of Health – both in Serbia and in Montenegro. In February 2003, a regulation on labeling was issued by the Serbian Ministry of Health. However, this regulation is incomplete and is not being applied. According to this regulation, all retail food labels on products with biotech content (0.9 percent minimum) must include a yellow triangle, framed with a red border and containing the letters in English “GMO” (black letters). However, there are no specific instructions for the actual label text. All commercial food and feed products should be labeled. There are indications that a more specific regulation on labeling will be issued next year, in accordance with EU rules.

### ANNEX

List of additional resources available from FAS Office Belgrade, Serbia and Montenegro Tel: ++ 381 11 306 4927; Fax: ++ 381 11 306 4922.

- 1) “Law on genetically modified organisms”  
Issued May 8, 2001; “Official Gazette No. 21/2001
- 2) Regulation (Rulebook) on “Commercial release of ‘GMOs’ or products derived from same” Issued November 13, 2002; No. 1245/1
- 3) Regulation (Rulebook) on “Contained use of genetically modified organisms”  
Issued November 13, 2002; No.1244/1
- 4) Regulation (Rulebook) on “Deliberate release of biotech products into the environment “ Issued November 13, 2002; No. 1246/1
- 5) Regulation (Rulebook) on “The content and data of products derived from GMOs”  
Issued December 15, 2002; No.1669/1
- 6) Regulation (Rulebook) on “Labeling of genetically modified products”  
Issued February 27, 2003; No. 16/18